CLAIMS

- 1 1. Complexes of paroxetine, as free base or as salt, with a cyclodextrin or with a cyclodextrin derivative.
- 2. Complexes as claimed in claim 1 characterised by the form of a flowing powder,
- chemical stability, absence of organic solvents, high solubility in water and DSC
- 3 profile different from that of the corresponding non-complexed paroxetine or
- 4 paroxetine salt.
- 3. Complexes as claimed in claim 2 characterised by the absence of ethanol.
- 4. Complexes as claimed in claim 1 characterised in that they have a water content of between 1 and 20% by weight.
- 5. Complexes as claimed in claim 4 characterised in that said water content is
- between 2 and 15% by weight.
 - 6. Complexes as claimed in claim 1, characterised in that said cyclodextrin is
 - selected from the group consisting of α , β and γ -cyclodextrin.
- 7. Complexes as claimed in claim β , characterised in that said cyclodextrin is a β -
- 2 cyclodextrin.

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- 1 8. Complexes as claimed in claim 1, characterised in that said cyclodextrin
- 2 derivative is selected from the group consisting of eptakis (2,6-di-O-methyl)-β-
 - 3 cyclodextrin, eptakis (2,3,6-tri-O-methyl)-β-cyclodextrin, monosuccinyl-eptakis(2,6-
 - 4 di-O-methyl)-β-cyclodextrin 2-hydroxypropyl-β-cyclodextrin, sulphated cyclodextrin
 - and cyclodextrin containing aminoalkyl groups.
 - 9. Complexes as claimed in claim 8, characterised in that said cyclodextrin
 - 2 derivative is the 2-hydroxypropyl-β-cyclodextrin.
 - 1 10. Complexes as claimed in claim 1, characterised in that said salt of paroxetine
 - 2 is a salt with an organic or inorganic acid.
 - 1 11. Complexes as claimed in claim 10, characterised in that said organic or
 - inorganic acid is selected from the group consisting of acetic acid, maleic acid,
 - 3 hydrochloric acid and methanesulfonic acid.
 - 1 12. Complexes as claimed in claim 11 characterised in that said acid is
 - 2 hydrochloric acid.
 - 13. Complexes as claimed in claim 1, characterised in that the molar ratio between
 - paroxetine and said cyclodextrin or cyclodextrin derivative ranges from 1:0.25 to

- 3 1:20.
- 1 14. Complexes as claimed in claim 13, characterised in that the molar ratio
- 2 between paroxetine and said cyclodextrin or cyclodextrin derivative ranges from
- 3 1:0.5 to 1:2.
- 15. Process for the preparation of the complexes as defined in claim 1, comprising
- the following steps:
- 3 (a) paroxetine, as free base or as salt, a cyclodextrin or a cyclodextrin derivative
- 4 and water are mixed;
- 5 (b) the obtained mixture is stirred in order to obtain an homogeneous solution or
- dispersion and stirring is continued until formation of the complex; and
- $\frac{1}{3}$ 7 (c) the water is partially removed in order to obtain a solid complex with the
- desired water content.
- 11 16. Process as claimed in claim 15 characterised in that paroxetine is used as a
- i free base.
 - 1 17. Process as claimed in claim 15 characterised in that paroxetine is used as a
- 1 2 salt.

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- 18. Process as claimed in claim 15 characterised in that step b) is carried out by
- 2 mechanical stirring or by ultrasounds.
- 19. Process as claimed in claim 15 characterised in that step c) is carried out by
- freeze drying, drying under vacuum or under an inert gas flux.
- 20. Process as claimed in claim 15 characterised in that in step c) a solid complex
- with a water content of between 1 and 20% by weight is obtained.
- 21. Process as claimed in claim 20 characterised in that said water content is
- between 2 and 15% by weight.
- 22. Process as claimed in claim 16 characterised in that step a) is carried out
- 2 according to the following steps:
- a₁) a cyclodextrin or a cyclodextrin derivative is added to water;
- a₂) the solution or dispersion of step a₁) is kept under stirring for a time from 30 to
- 5 180 minutes at a temperature between 25° and 50°C; and
- 6 a₃) paroxetine base is dispersed in the solution or dispersion of step a₂).
- 23. Process as claimed in claim 17, characterised in that said step a) is carried out
- 2 according to the following steps:

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- a₁) paroxetine base is salified with an organic or inorganic acid; and
- 4 a₂) a cyclodextrin or a cyclodextrin derivative is added under stirring to the salified
- 5 paroxetine.
- 24. Process as claimed in claim 16 characterised in that step c) is carried out
- 2 according to the following steps:
- 3 c₁) the dispersion of step b) is cooled and maintained at a temperature between
- 4 4°C and 20°C for 1 to 20 hours;
- 5 c₂) the precipitate obtained in step c₁) is recovered by filtration; and
- c_3) the solid product recovered in step c_2) is dried under vacuum or under an inert gas flux until the desired water content is reached.
- 1 25. Process for the preparation of complexes as claimed in claim 1 comprising
- slowly adding paroxetine base in the form of an oily liquid to a cyclodextrin or to a
- 3 cyclodextrin derivative in a mixer for powders or in an ultrasonic mixer and
 - continuing the stirring for a time ranging from 3 to 24 hours at a temperature from
- 5 25 to 50 °C.

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- Pharmaceutical compositions containing as an active substance a pharmaceutically effective dose of a complex as defined in claim 1, in mixture with
 - 3 pharmaceutically acceptable diluents or excipients.
 - 27. Pharmaceutical compositions as claimed in claim 26 in solid or liquid form, for
 - oral and for parenteral administration.
 - 28. Therapeutical method for the treatment of patients suffering from depression or
 - 2 Parkinson's disease or other pathologies curable with paroxetine consisting of the
 - administration of a complex as defined in claim 1, in an amount corresponding to
 - 5-40 mg per day of paroxetine by oral way and corresponding to 1-20 mg per day
 - of paroxetine parenterally.

